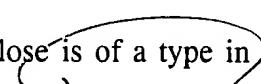


Clean Copy of Amended Claims

1. 1. A thermal adhesion granulation process for preparing direct tabletting formulations or aids, comprising the step of subjecting all or part of a mixture comprising:
 3. A) from about 5 to about 99% by weight of one or more diluent excipients and/or from 0 to about 99% by weight of a pharmaceutically-active ingredient;
 5. B) from about 1 to about 95% by weight of a binder excipient; and
 6. optionally with,
 7. C) from 0 to about 10% by weight of a disintegrant excipient;
8. to heating at a temperature range of from about ~~30~~ ^{room temp} to about 130°C under the condition of from about 0.1 to about 20% initial moisture content and/or from about 0.1 to about 20% initial content of a pharmaceutically-acceptable organic solvent in a closed system under mixing by tumble rotation until the formation of granules.
1. 2. A process as defined in claim 1, wherein the temperature range is from about 40 to about 110°C.
1. 3. A process as defined in claim 1, wherein the temperature range is from about 60 to about 105°C.
1. 4. A process as defined in claim 1, wherein the initial moisture content is from about 2 to about 15%.
1. 5. A process as defined in claim 1, wherein the initial moisture content is from about 4 to about 10%.

- 1 6. A process as defined in claim 1, wherein the initial organic solvent content is from about
- 2 0.1 to about 10%.
- 1 7. A process as defined in claim 1, where the initial organic solvent content is from about
- 2 0.5 to about 5%.
- 1 8. A process as defined in claim 1, wherein the diluent excipient is powdered cellulose,
- 2 microcrystalline cellulose, lactose, starch, or dibasic calcium phosphate.
- 1 9. A process as defined in claim 1, wherein the pharmaceutically-active ingredient is
- 2 acetaminophen or ascorbic acid.
- 1 10. A process as defined in claim 1, wherein the binder excipient is soluble polyvinyl
- 2 pyrrolidone or hydroxypropylcellulose.
- 1 11. A process as defined in claim 1, wherein the disintegrant excipient is crospovidone,
- 2 sodium starch glycolate, reticulated carboxymethylcellulose, or low-substituted
- 3 hydroxypropylcellulose.
- 1 12. A process as defined in claim 1, wherein the diluent excipient is microcrystalline
- 2 cellulose.
- 1 13. A process as defined in claim 12, wherein the microcrystalline cellulose is of a type in 
2 which about 90% of the particles are in the range from about 1 μm to about 125 μm , and
3 the average particle size is from about 10 μm to about 70 μm .
- 1 14. A process as defined in claim 1, wherein the binder excipient is soluble polyvinyl
- 2 pyrrolidone.

- 1 15. A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K
- 2 value of from about 12 to about 120.
- 1 16. A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K
- 2 value of from about 20 to about 95.
- 1 17. A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K
- 2 value of from about 25 to about 35.
- 1 18. A process as defined in claim 1, wherein the binder excipient further contains from 0 to
- 2 about 10% (by weight with respect to the binder) of an anticaking agent.
- 1 19. A process as defined in claim 18, wherein the binder excipient contains from about 0.01
- 2 to about 10% (by weight with respect to the binder) of an anticaking agent.
- 1 20. A process as defined in claim 18, wherein the binder excipient contains from about 2 to
- 2 about 4% (by weight with respect to the binder) of an anticaking agent.
- 1 21. A process as defined in claim 18, wherein the anticaking agent is dibasic calcium
- 2 phosphate anhydrous.
- 1 22. A product of thermal adhesion granulation process for preparing direct tableting
- 2 formulations or aids as defined in claim 1.
- 1 23. A powder mixture of soluble polyvinyl pyrrolidone containing from about 0.01 to about
- 2 10% (by weight with respect to the polyvinyl pyrrolidone) of dibasic calcium phosphate
- 3 anhydrous.
- 1 24. A direct tableting formulation or aid comprising:

2 i) from about 5 to about 99% by weight of powder cellulose, microcrystalline cellulose,
3 lactose, starch, or dibasic calcium phosphate;
4 ii) from 0 to about 99% by weight of acetaminophen or ascorbic acid;
5 iii) from about 1 to about 95% by weight of a soluble polyvinyl pyrrolidone which
6 contains from about 0.01 to about 10% (by weight with respect to the polyvinyl
7 pyrrolidone) of dibasic calcium phosphate anhydrous; and
8 iv) from 0 to about 10% by weight of crospovidone, sodium starch glycolate, reticulated
9 carboxymethylcellulose, or low-substituted hydroxypropylcellulose.

1 25. A tablet which comprises a product as defined in claim 22.

1 26. A tablet which comprises the powder mixture as defined in claim 23.

1 27. A tablet which comprises a tabletting formulation or aid as defined in claim 24.

1 28. A capsule which comprises a product as defined in claim 22.

1 29. A capsule which comprises a powder mixture as defined in claim 23.

1 30. A capsule which comprises a tabletting formulation or aid as defined in claim 24.

1 31. A pellet which comprises a product as defined in claim 22.

1 32. A pellet which comprises a powder mixture as defined in claim 23.

1 33. A pellet which comprises a tabletting formulation or aid as defined in claim 24.